

k002201



**SMITHS INDUSTRIES**

*Medical Systems*

**FEB - 5 2001**

**SIMS Portex Inc.**

10 Bowman Drive

PO Box 0724

Keene NH 03431 USA

Telephone: 603-352-3812

Fax: 603-352-3703

**H: 510(K) SUMMARY OF SAFETY  
AND EFFECTIVENESS**

**510(K) SUMMARY:**

**COMPANY INFORMATION:**

SIMS Portex Inc  
10 Bowman Drive  
Keene, NH 03431  
(603) 352-3812  
Contact: Timothy J. Talcott  
Director, Regulatory Compliance

**PREPARATION DATE OF SUMMARY:**

July 18, 2000

**TRADE NAME:**

Electrostatic Hydrophobic Breathing Filter

**COMMON NAME:**

Breathing Circuit Bacterial Filter

**PRODUCT CLASS/CLASSIFICATION:**

Class II, 73 CAH, 21 CFR 868.5260

**PREDICATE DEVICE(S):**

SIMS Portex Inc. Breathing Filter, catalog number 002832, K830618;  
Intersurgical Inc., Caxenovia, NY, Filta-Guard, Catalog number 1944.

## **DESCRIPTION:**

The SIMS Electrostatic Hydrophobic Breathing Filter is a breathing device used to reduce the transmission of micro organisms in gases delivered to and exhaled from patients and breathing systems. This device contains a hydrophobic filter membrane and an electrostatic filter media made of polypropylene housed within a transparent blue tinted shell. It features a 15 mm I.D./ 22 mm O.D. patient port with anti-disconnect recess, and a 22 mm I.D./15 mm O.D. machine port. Integral gas sampling port with cap is included on the machine end.

The hydrophobic membrane prevents patient fluids from reaching the electrostatic filter media. The hydrophobic membrane separates water from the electrostatic filter media, which could diminish the charge. This enhances the microbial removal efficiency of the breathing filter.

The device is intended for single use only, during anesthesia and ventilatory support. This device is supplied non-sterile with 15 and 22mm connectors and a gas sampling port.

## **INDICATIONS FOR USE:**

For use with ventilators, anesthesia machines and open flow systems where filtration of inspired or expired gases is required. The filter may be positioned at the machine end of the expiratory and/or inspiratory limb of the circuit, or at the patient end of the circuit. When at the patient end, the tidal volume should exceed 300 ml.

## **TECHNICAL CHARACTERISTICS:**

The filter has the following technical specifications:

Filter efficiency*	>99.999% BFE >99.997% VFE
Weight	32 grams
Pressure Drop (Resistance to Flow)	<5 cmH <sub>2</sub> O @ 60 LPM
Compressible Volume (Dead Space)	55 ml (Nominal)
Connections	15 mm I.D. x 22 mm O.D. @ patient end 22 mm I.D. x 15 mm O.D. @ machine end
Hydrohobicity	>30 cmH <sub>2</sub> O

\* Tested per Mil-M-36954C, particle challenge range 0.3 to 10 $\mu$  using Staphylococcus aureus bacteria (mean particle size 1 $\mu$ ) and using Bacteriophage PHI X 174 virus (mean particle size 0.027 $\mu$ ).

**NON-CLINICAL DATA:**

Performance and specifications of the filter meet the requirements of the following standards:

ISO 5356-1; Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.

ISO 594-2; Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings.

ISO 9360; Anaesthetic and respiratory equipment – Heat and moisture exchangers for humidifying respired gases in humans, as it pertains to resistance to flow, compressible volume, and leakage.

In addition, data submitted demonstrates that the device meets all technical specifications listed in the above paragraph.

**CONCLUSION:**

The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

Very truly yours,

SIMS PORTEX INC.

A handwritten signature in black ink, appearing to read "Timothy J. Talcott", with a long, sweeping horizontal line extending to the right.

Timothy J. Talcott  
Director, Regulatory Compliance



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 5 2001

Mr. Timothy J. Talcott  
SIMS Portex Inc.  
10 Bowman Drive  
P.O. Box 0724  
Keene, NH 03431

Re: K002201  
Electrostatic Hydrophobic Breathing Filter  
Regulatory Class: II (two)  
Product Code: CAH  
Dated: November 15, 2000  
Received: November 16, 2000

Dear Mr. Talcott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

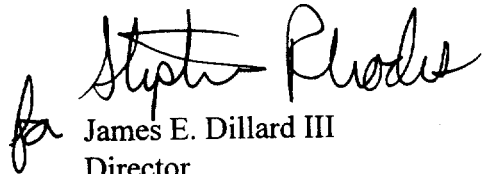
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is stylized with a large "J" and "D".

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## B: INTENDED USE OF DEVICE

### PROPOSED INDICATIONS FOR USE:

Page 1 of 1

510(k) Number (if known): Unknown K002201

Device Name: Electrostatic Hydrophobic Breathing Filter

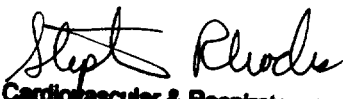
#### Indications For Use:

For use with ventilators, anesthesia machines and open flow systems where filtration of inspired or expired gases is required. The filter may be positioned at the machine end of the expiratory and/or inspiratory limb of the circuit, or at the patient end of the circuit. When at the patient end, the tidal volume should exceed 300 ml.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The-Counter Use ☐

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K002201